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## RESEARCH/CLINICAL UPDATE

<b>Keyword:</b>	Testosterone
<b>Section:</b>	TREATMENTS, INVESTIGATIONAL

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### **Positive Results Published on Testosterone for Men with MS**

Researchers from the University of California, Los Angeles have published results from a small study, funded by the National MS Society and others, suggesting that one year of treatment with a gel containing the sex hormone testosterone (applied to the skin) in 10 men with relapsing-remitting multiple sclerosis resulted in significant improvements in cognitive function and in slowing brain tissue loss. Nancy Sicotte, MD, Rhonda Voskuhl, MD, and colleagues report these positive findings in the May 2007 issue of *Archives of Neurology* ([2007;64:683-688](#)).

Further research involving larger numbers of patients and controls would help to confirm and expand these early results, and to ensure the safety and effectiveness of testosterone treatment in MS.

**Background:** Sex hormones may contribute to MS susceptibility by influencing the immune attack on brain and spinal cord tissues. Laboratory studies have shown that the severity of EAE, an MS-like disease, is decreased when testosterone, a male sex hormone, is administered to male and female mice. Dr. Voskuhl was awarded funding from the National MS Society's targeted research initiative on [Gender Differences in MS](#) to undertake a small study of testosterone gel in men with MS. Preliminary results of this study were originally presented at the 58th Annual Meeting of the American Academy of Neurology in April 2006.

**Study:** Ten men with relapsing-remitting MS, ranging from 29 to 61 years of age, were studied. Relapsing-remitting MS is the most common form of the disease, involving clearly defined flare-ups followed by partial or complete recovery periods. After a six-month observation period, they were treated with testosterone gel applied to the skin (10 grams daily, containing 100 mgs of testosterone) for one year. None of the men were taking [disease-modifying therapies](#). Clinical assessments including blood tests, as well as clinical measures of disease

activity and cognitive function were completed every three months. [Magnetic resonance imaging](#) scans were taken before treatment and monthly to measure evidence of disease activity. The extent of brain tissue loss (atrophy) was assessed by determining normalized brain volumes using automated computer software.

Since all 10 of the men received treatment and none received inactive placebo, the investigators compared measures taken before treatment versus after treatment. Testosterone levels were in the lower range of normal before treatment, and although they increased with treatment, remained in the normal range.

After 12 months of testosterone treatment, measures of clinical disease activity remained stable, blood tests were normal, and no adverse events related to treatment were reported. The men showed significant improvements in performance on a test of cognitive function called the [Paced Auditory Serial Addition Task](#) (a test of processing speed and memory) compared to the pre-treatment period. The authors report that the improvement could not be accounted for by well-known “practice effects,” which had stabilized during the pre-treatment period.

MRI scans showed no increases in disease activity or tissue damage during treatment, although the authors note that the patients began the study with relatively low levels of disease activity on MRI.

Significantly, the rates of brain atrophy, measured by normalized brain volume, slowed by 67 percent during the last nine months of treatment. Muscle mass increased significantly during the study; testosterone is sometimes used for this purpose in other chronic diseases.

This small study shows that testosterone treatment may have therapeutic benefit in men with relapsing-remitting MS. Further study involving larger numbers of patients and control groups is necessary to confirm these early results, and to ensure the safety and effectiveness of testosterone treatment for MS.

“We’re gratified that these early, promising results stemmed from the National MS Society’s targeting of gender differences as an important area of research in MS,” said Dr. John R. Richert, the Society’s executive vice president of research. “It also demonstrates how basic laboratory findings can quickly translate into possible new therapeutic strategies.”

Dr. Voskuhl and colleagues are already proceeding with a similar effort involving the sex hormone estradiol: Based on a small, early-phase trial that showed decreases in disease activity in 12 women with MS, she is now launching a multicenter, controlled [clinical trial of oral estradiol](#) (added to the approved MS therapy glatiramer acetate) in 130 women with relapsing-remitting MS.

-- Research and Clinical Programs

